REMARKS

Claims 1-36 are pending in this application. Claims 1-17 have been withdrawn as being directed to non-elected subject matter.

Independent claim 18 is directed to "sponge for iontophoretic administration of charged drugs to a tissue of a subject, comprising: a porous structure configured to absorb and hold at least 30% w/w of an aqueous solution of a charged drug without dissolving or disintegrating, the porous structure comprising a tissue contacting surface area; and a data transmitting module configured and operable to transmit data indicative of one or more of sponge size and the tissue contacting surface area the sponge with the tissue of the subject." Support for the amendment to clam 18 can be found throughout the specification and claims as originally filed. Claims 19-36 depend, either directly or indirectly, from claim 18.

Claim 36 has been added. New claim 36 is directed to the "sponge according to claim 18, wherein when an electrical current is passed through the porous structure of the sponge, and the sponge is pre-loaded with the aqueous solution, the drug ejects from the tissue contacting surface area." Support for new claim 36 can be found throughout the specification and claims as originally filed.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

I. At page 3 of the Official Action, claims 18-22, 26-29, 31-35 have been rejected under 35 USC § 103(a) as being unpatentable over Jacobsen et al. (US 4,250,878) in view of Sun et al. (US 2002/0115957).

The Examiner asserts that it would have been obvious to modify the device described by Jacobsen et al. with a data transmitting module capable to transmit data indicative of one or more of sponge size.

In view of the following these rejections are respectfully traversed.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.,* 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must

teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

In addition, **MPEP 2143** states that where the prior art conflicts, all teachings must be considered and that the fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. **MPEP 2143** further states that there must be some suggestion or motivation to modify the references, and there must be a reasonable expectation of success.

MPEP 2143.01 states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest every element of the claimed subject matter. Further there is no motivation to modify Jacobsen et al., because Jacobsen et al. *teach away* from the presently claimed subject matter. Further, it is submitted that the combination of Jacobsen et al. with Sun et al. would render Jacobsen et al. unsatisfactory for its intended purpose. *See* **MPEP 2143.01.**

Claim 18 is directed to a sponge for iontophoretic administration of charged drugs to a tissue of a subject, comprising: a porous structure configured to absorb and hold at least 30% w/w of an aqueous solution of a charged drug without dissolving or disintegrating, the porous structure comprising a tissue contacting surface area; and a data transmitting module configured and operable to transmit data indicative of one or

more of sponge size and the tissue contacting surface area the sponge with the tissue of the subject. Claims 19-22, 26-29 and 31-34 depend, either directly or indirectly, from claim 18,

In contrast, Jacobsen et al. is directed to a bioelectrode for ***non-invasive*** and inotophoretic delivery of a chemical species into the skin of a person. The bioelectrode according to Jacobsen et al. includes a pouch having flexible walls, at least a portion of which is composed of a microporous, permeable or semipermeable membrane. According to Jacobsen et al., the pouch holds fluid which contains the chemical species to be delivered through the skin. An electrode is attached to the pouch so that when the pouch is placed against the skin, with the membrane portion in contact with the skin, and an electric potential is applied to the electrode, chemical species in the pouch are caused to migrate through the membrane and into the skin. *See* Jacobsen et al. at the abstract.

The chemical species of Jacobsen are contained within the pouch, and the membrane itself is absent of chemical species when electric potential is not applied. The ***chemical species are only present in the membrane for the transient period of time during the use of the electrode***; the chemical species are driven through the membrane when an electric potential is activated, and are not retained therein. *See* Jacobson et al., for example, at page 2, lines 27-33, page 3, lines 20-2, and page 4, lines 28-31. As a result, the membrane of Jacobsen et al., which is the part that comes into contact with the skin, cannot hold the solution of the chemical species, but rather serves as a transition layer between the pouch and the skin.

In contrast, the presently claimed sponge does not have a "membrane layer;" rather the sponge is configured to come in direct contact with the skin. As recited in the present claims, the solution of the drug may be held in the porous structure, and discharged from it upon activation of an electrical current. According to the presently claimed subject matter, there is no layer functioning to retain the liquid within the porous structure when the sponge is not in use, i.e., ***the porous structure itself retains and holds the solution within the sponge when no electrical current is applied***.

Moreover, the pouch of Jacobsen can be best described as a "bag," having two generally facing walls (page 3, lines 10-11), with a liquid contained in the space formed between the walls. In the present invention, the liquid is held within and by the porous structure, and not by any external constraints such as an enveloping membrane.

Jacobsen et al. describe placing of the pouch, which surrounds a reservoir maintaining chemicals against the skin. In line with this principle of operation, Fig. 6 shows an elongated bioelectrode for inserting into a body cavity or an orifice. Jacobsen et al. ***requires*** that the reservoir which maintains the chemicals is ***always*** surrounded by an exterior wall, i.e., referred to as a pouch (82) completely surrounding the sponge element (86). However, unlike the presently claimed subject matter, ***the sponge element is, therefore, never in contact with a tissue.***

Sun et al. is directed to an apparatus for transporting a compound through a barrier membrane of a mammal. Sun et al. describes that a "chemical carrier that interacts with the active agent (e.g., drug), for example, by encapsulation, entrapment, surface adsorption or other mechanisms to form a microscopic drug delivery system,"

can be used. Examples of chemical carriers are the following: "(a) liposomes; …(d) microcapsules; …and (g) nanoparticles."

However, whether taken alone or together, Jacobson et al. and Sun et al. do not teach or suggest a sponge…comprising…***a porous structure configured to absorb and hold at least 30% w/w of an aqueous solution of a charged drug***, as claimed. Once again, Applicants maintain that none of the cited references teach or suggest an inotophoretic sponge for delivery of a ***charged*** drug. Accordingly, all of the elements of the presently claimed subject matter are not taught or suggested, as required by *In re Wilson*.

In addition, Applicant submits that there is no suggestion or motivation to modify the apparatus of Jacobsen et al. to remove the exterior pouch/wall such that the sponge would directly contact tissue, because Jacobsen et al. specifically require the pouch/wall in order to "…retain fluid in a relatively leak-free manner" and to "allow retention and storage of the fluid in the receptacle…." *See* Jacobsen et al. at col. 1, lines 34-48; and col. 2, lines 2, lines 4-6.

In fact, Jacobsen et al. clearly ***teach away*** from employing a sponge absent a pouch/wall. Jacobsen et al., at col. 1, lines 37-48, state the following:

> It has been suggested that a wicking material be placed over the opening of the bioelectrode receptacle to improve the uniformity of contact between the fluid and the skin surface. Such an arrangement although reducing spillage, ***does not allow retention and storage of the fluid in the receptacle*** since, if fluid were introduced into the receptacle long prior to use, the ***fluid would tend to flow through and evaporate from the wicking material***. Also, ***any substantial pressure on a filled receptacle would tend to accelerate the flow of fluid through and out of the wicking material***. (emphasis added)

Clearly, the skilled artisan reading the above passage, would have no motivation to remove the pouch from the device of Jacobsen et al. since the result would be the undesirable loss of fluid, and the inability to retain and store the receptacle containing fluid. Regarding *teaching away*, **MPEP 2141.02** states that prior art must be considered in its entirety, including disclosures that *teach away* from the claims. *See also* **MPEP 2145(X)(D)**.

Further, Applicant submits that modifying the apparatus of Jacobsen et al. to remove the exterior pouch/wall such that the sponge would directly contact tissue, would render the device of Jacobsen et al. unsatisfactory for its intended purpose because the device of Jacobsen et al. requires a pouch for the purpose of minimizing the loss of fluid which loss is "both wasteful and messy," and to "allow retention and storage of the fluid in the receptacle." *See* Jacobsen et al. at col. 1, lines 34-48; and col. 2, lines 2, lines 4-6. *See also* **MPEP 2143.01** which states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it ***does***, then there is ***no suggestion or motivation to make the proposed modification.*** Further, the proposed modification cannot change the principle operation of a reference.

In view of the foregoing, it is submitted that nothing in the cited references, whether taken alone, or together, render the claimed invention obvious within the meaning of 35 USC § 103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At page 4 of the Official Action, claims 23-25 and 30 have been rejected under 35 USC § 103(a) as being unpatentable over Jacobsen et al. in view of Sun et al. in further view of Nicolais et al. (US 5,645,592).

The Examiner asserts that it would have been obvious to have modified the sponge of Jacobsen/Sun by coating it with HEMA-methyl methacrylate copolymer as taught by Nicolais for the purpose of increasing water absorption.

In view of the following these rejections are respectfully traversed.

A brief discussion of the relevant authority on obviousness is set forth in § I above.

In addition, independent claim 18, Jacobsen et al. and Sun et al. are also discussed in detail above. Applicants note that claims 23-25 and 30 each depend, either directly or indirectly from claim 18.

As discussed, whether taken alone or in combination, Jacobsen et al. and Sun et al. do not teach or suggest a sponge having tissue contacting surface area, a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution of charged drug, as recited in claim 18. In addition, there is no motivation to modify Jacobsen et al. and Sun et al. for the reasons discussed in § 1 above.

Nicolais et al. do not remedy the deficiencies of Jacobsen et al. and Sun et al. Nicolais merely discloses a hydrogel comprising HEMA-methyl methacrylate copolymer, and cannot be configured by the disclosures of Jacobson et al. nor Sun et al. to provide the presently claimed subject matter.

Therefore, Applicants submit that, whether taken alone or together, none of the cited references teach or suggest a sponge having surface area of contact with the tissue, a porous structure which is capable of absorbing and holding at least 30% w/w of

an aqueous solution without dissolving or disintegrating or a data transmitting module configured and operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject. Accordingly, Applicants submit that the presently claimed subject matter is not obvious.

In view of the foregoing, it is submitted that nothing in the cited references, whether taken alone, or together, render the claimed invention obvious within the meaning of 35 USC § 103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. New claim 36.

Claim 36 has been newly added. Applicants respectfully submit that new claim 36 is also novel and non-obvious. Thus, Applicants submit that all of the pending claims are in condition for immediate allowance.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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Date: September 1, 2011
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